Specification for Transmitting Electronic Submissions using eCTD Specifications

Revision History

Date	Version	Summary of Changes
2005-05-25	1.0	Original version
2005-06-14	1.1	Correction of typographical error in Type of Media table
2009-08-27	1.2	Removal of Media Type Floppy Disk Updated LTO specifications Added information regarding ESG
2010-08-02	1.3	Change to Address for electronic submission sent on physical media CDER Office of Generic Drugs address change
2011-12-28	1.4	Added information regarding USB media format Added retirement date for Tape options Added email address for Questions/Communication with Centers
2012-07-26	1.5	Clarification that USB encryption is optional Rewording information regarding password protection of data vs. USB drive

Specification for Transmitting Electronic Submissions using eCTD Specifications

This document provides specification for transmitting electronic submissions using eCTD specifications. Details are included for transmitting the electronic submission on physical media or electronically.

I. ELECTRONIC TRANSMISSION

FDA prefers to receive submissions via the Electronic Secure Gateway (ESG) rather than on physical media. Whenever possible, please use the ESG. See
http://www.fda.gov/ForIndustry/ElectronicSubmissionsGateway/default.htm
for more information.

II. PHYSICAL MEDIA

A. Address for electronic submissions sent on physical media

CBER:

U.S. Food and Drug Administration
Center for Biologics Evaluation and Research
Document Control Center
1401 Rockville Pike, HFM-99
Rockville, MD 20832-1448

CDER:

U.S. Food and Drug Administration
Center for Drug Evaluation and Research
Central Document Room
5901-B Ammendale Rd.
Beltsville, MD 20705-1266

U. S. Food and Drug Administration
Office of Generic Drugs – HFD-600
Center for Drug Evaluation and Research
Metro Park North II
7500 Standish Place, Rm. 150
Rockville, MD 20855-2773

B. Types of physical media accepted

See the following table:

Type of media	Format	Size
CD ROM	CD-R Joliet Specification	Up to 3 GB (1- 5 CDs)
DVD	DVD-R DVD+R DVD+/-R	Up to 45 GB (1 to 6 DVDs)
Digital Linear Tape DLT-IV*	35/70 or 40/80 DLT tapes using BackupExec, or Windows 2000/2003 native backup	No limit (contact Agency Center for any submission over 45 GB)
Linear Tape Open LTO*	LTO 1, 2, 3, or 4 tapes using BackupExec, or Windows 2000/2003 native backup	No limit (contact Agency for any submission over 45 GB)
USB drive	• Device Type: External hard drive Size not to exceed: Width: 4 in Depth: 5 in Height: 1 in • Interface: Hi-Speed USB 2.0 with a Type A connector • Passcode: use 6 to 24 digits (optional) • Compliant Standards: 128-bit AES (Advanced Encryption Standard) • Driverless operation • Built-in USB cable with included power source: USB Bus	Over 45 GB only (contact the Agency Center in advance for specific instructions on how to send – see below for email addresses) IMPORTANT: DO NOT SUBMIT USB DRIVES FOR SUBMISSIONS UNDER 45 GB

****THESE TAPE FORMATS WILL BE RETIRED ON 12/31/2012***

IMPORTANT: Do not compress data. Do not password protect any data. The only exception is the optional passcode encryption of a USB drive.

C. Media preparation

Send all electronic media adequately secured in a standard binder marked clearly on the outside ELECTRONIC REGULATORY SUBMISSION FOR ARCHIVE. Do not send unlabeled media.

The following information should be included on the media labels:

Sponsor, applicant or company name
Name of the product, chemical or ingredient
Appropriate regulatory ID number (e.g., NDA application number)
Submission date (dd-mmm-yyyy)
Media series (e.g., “1 of 1”, “1 of 2”)

Questions may be sent to:
CDER: ESUB@fda.hhs.gov
CBER: ESUBPREP@fda.hhs.gov